DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	11/17/2025-12/16/2025* FEI NUMBER 3017397160

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David L. Greene, CEO

FIRM NAME	STREET ADDRESS
Regen Suppliers LLC	10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Scottsdale, AZ 85262-3752	Biological Product Distributor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures describing the handling of all written and oral complaints regarding a drug product are not established.

Specifically, since beginning operations in January 2021 your firm has not established or approved your written procedures for handling consumer complaints entitled "Regen Suppliers- Customer Complaint Standard Operating Procedures" that are still in draft form.

For example, per these draft procedures under section (b) (4) titled (b) (4) for which your firm defines as any complaint involving (b) (4), must be investigated by Quality Control and Operations within (b) (4) (b) (4).

- Your firm does not have a designated Quality Control unit as explained in Observation Number 2.
- Your firm received the following two complaints in 2025 that represented a serious adverse event and were not investigated:

Adverse Event # 1

On November 9th, 2025, your firm received a compliant which stated three patients had been hospitalized with meningitis after product was administered intrathecally. The administered product was determined to be (b) (4) -lot (b) (4) received by your customer on 10/28/2025 and labeled as "(b) (4)". Per your customers request your firm provided sterility and communicable disease testing from your Cord Blood supplier (b) (4). This complaint case was then closed without further investigation.

Upon further review of the complaint during this inspection, it was determined that the following products and lots were also provided to your customer who reported the adverse event on 10/28/2025:

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	Garrad R Poole, Investigator Laurissa S Flowers, Investigator Emily S Mcgann, Investigator X Garrad R Poole Investigator Signed By: GARRAD R. POOLE - S Date Signed: 12-16-2025 08:49:47	12/16/2025

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Date Delivered	Product/Lot	Manufacturer
9/23/2025	(b) (4) lot (b) (4) (b) (4)	(b) (4)
9/23/2025	(b) (4) lot (b) (4) (b) (4)	(b) (4)
10/28/2025	(b) (4) lot (b) (4) (b) (4)	(b) (4)
10/28/2025	(b) (4) lot (b) (4) (b) (4)	(b) (4)
10/28/2025	(b) (4) lot (b) (4) (b) (4)	(b) (4)

Adverse Event #2

On September 3, 2025, your firm initially received a complaint after a patient received an injection from one of your customers. According to your email chain following this complaint, the patient stated that they experienced bone pain that radiated from their back to their pelvis after receiving an injection of (b) (4) is manufactured by your contract manufacturer, (b) (4) (b) (4) of the event. There was no documentation showing that a review of the complaint had been conducted until December 4, 2025, after the FDA conducted a MedWatch follow-up at your customer who administered the injections and notified you that they were on-site.

Your firm markets and distributes human umbilical cord-derived products that include but are not limited to:

Wharton's Jelly and Exosome Products:

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- Private labels: (b) (4)
- Customer private labels: (b) (4)

Umbilical Cord Blood Products:

- Private label: (b) (4)
- Customer private labels: (b) (4)

Respectively, your firm has distributed (b) (4) units marketed as Whartons Jelly labeled for (b) (4) (b) (4) units marketed as exosomes labeled for " (b) (4) units marked as growth factor labeled for " (b) (4) ", and (b) (4) units marked as cord blood marketed and labeled for " (b) (4) ".

OBSERVATION 2

There is no quality control unit.

Specifically, since beginning operations in January 2021 your firm has not established a quality control unit with the responsibility and authority to oversee the labeling, storage, release, distribution, and complaint investigation of your umbilical cord and umbilical cord blood products.

Additionally, on 12/10/2025 your firm signed an agreement for manufacturing and direct distribution to customers with the contract manufacturer (b) (4) without qualifying them as a supplier.

Your firm markets and distributes human umbilical cord-derived products that include but are not limited to:
Wharton's Jelly and Exosome Products:

- Private labels: (b) (4)
- Customer private labels: (b) (4)

Umbilical Cord Blood Products:

- Private label: (b) (4)
- Customer private labels: (b) (4)

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Respectively, your firm has distributed (b) (4) units marketed as Whartons Jelly labeled for (b) (4) (b) (4) units marketed as exosomes labeled for (b) (4) units marked as growth factor labeled for (b) (4) and (b) (4) units marked as cord blood marketed and labeled for "(b) (4)".

OBSERVATION 3

After the completion of the donor-eligibility determination, HCT/Ps were not accompanied with a statement whether the donor has been determined to be eligible or ineligible, based on the results of screening and testing.

Specifically,

a) Your firm provides a Certificate of Analysis (COA) to your customers which includes communicable disease testing results for your private label products (b) (4), and (b) (4). These COAs are provided to your firm by your contract manufacturer (b) (4). This COA is signed by the (b) (4) Medical Director, however, the certificate lacks:

- A statement of whether the donor is eligible or ineligible
- A statement of donor eligibility based of donor screening results
- A statement that the communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Act of 1988 or has met equivalent requirements determined by the Centers for Medicare and Medicaid Service.
- The address of the establishment reviewing the donor records documents to make a donor eligibility determination.

b) Your firm issues Certificates of Analysis (COAs) to customers for the private label product (b) (4), which include communicable disease testing results. While these COAs bear your contract manufacturer's name ((b) (4)), they originate from your cord blood manufacturer (b) (4). The COAs provided to customers lack a statement indicating donor eligibility status as follows:

- A statement of whether the donor is eligible or ineligible
- A statement of donor eligibility based of donor screening results

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- A statement that the communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Act of 1988 or has met equivalent requirements determined by the Centers for Medicare and Medicaid Service.
- The address of the establishment reviewing the donor records documents to make a donor eligibility determination.

Your firm markets and distributes human umbilical cord-derived products that include but are not limited to:

Wharton's Jelly and Exosome Products:
- Private labels: (b) (4)
- Customer private labels: (b) (4)

Umbilical Cord Blood Products:
- Private label: (b) (4)
- Customer private labels: (b) (4)

Respectively, your firm has distributed (b) (4) units marketed as Whartons Jelly labeled for (b) (4) (b) (4) units marketed as exosomes labeled for (b) (4) units marked as growth factor labeled for (b) (4) and (b) (4) units marked as cord blood marketed and labeled for (b) (4) .

OBSERVATION 4

Procedures designed to assure that correct labeling and packaging materials are used for drug products are not written.

Specifically, you have not established written procedures to include the review and approval of labels that are applied to finished product containers or labeling that is sent with product upon final packaging.

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Your firm markets and distributes human umbilical cord-derived products that include but are not limited to:

Wharton's Jelly and Exosome Products:
- Private labels: (b) (4)
- Customer private labels: (b) (4)

Umbilical Cord Blood Products:
- Private label: (b) (4)
- Customer private labels: (b) (4)

Respectively, your firm has distributed (b) (4) units marketed as Whartons Jelly labeled for (b) (4) (b) (4) units marketed as exosomes labeled for (b) (4) units marked as growth factor labeled for "(b) (4)", and (b) (4) units marked as cord blood marketed and labeled for "(b) (4)".

OBSERVATION 5

Drug product expiration dates do not appear on the labeling in the manner prescribed by regulations.

Specifically, your firm distributes private label cord blood under the brand (b) (4) that is manufactured by (b) (4). There is no expiration date on either the primary label or the Certificate of Analysis that accompanies the product.

Your firm markets and distributes human umbilical cord blood products under multiple brand labels:

Umbilical Cord Blood Products:
- Private label: (b) (4)
- Customer private labels: (b) (4)

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Respectively, your firm has distributed (b) (4) units marked as cord blood marketed and labeled for "(b) (4) (b) (4)".

OBSERVATION 6

Complaint procedures are deficient in that written complaint records are not maintained in a file designated for drug product complaints.

Specifically, per your draft written procedures entitled "Regen Suppliers-Customer Complaint Standard Operating Procedure" complaints can be received via (b) (4). There is no official complaint file to document or track such complaints.

Your firm markets and distributes human umbilical cord-derived products that include but are not limited to:

Wharton's Jelly and Exosome Products:

- Private labels: (b) (4)
- Customer private labels: (b) (4)

Umbilical Cord Blood Products:

- Private label: (b) (4)
- Customer private labels: (b) (4)

Respectively, your firm has distributed (b) (4) units marketed as Whartons Jelly labeled for (b) (4) (b) (4) units marketed as exosomes labeled for (b) (4) units marked as growth factor labeled for (b) (4) and (b) (4) units marked as cord blood marketed and labeled for (b) (4)

OBSERVATION 7

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A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary, has not been established.

Specifically, since beginning operations in January 2021 your firm has not established written procedure for recall operations.

Your firm markets and distributes human umbilical cord-derived products that include but are not limited to:

Wharton's Jelly and Exosome Products:

- Private labels: (b) (4)
- Customer private labels: (b) (4)

Umbilical Cord Blood Products:

- Private label: (b) (4)
- Customer private labels: (b) (4)

Respectively, your firm has distributed (b) (4) units marketed as Whartons Jelly labeled for (b) (4) (b) (4) units marketed as exosomes labeled for (b) (4) units marked as growth factor labeled for (b) (4) and (b) (4) units marked as cord blood marketed and labeled for (b) (4) .

OBSERVATION 8

The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary.

Specifically, during a review of your product transfer logs to customers that are tracked using Microsoft Excel spreadsheets, it was noted that records pertaining to lot distribution could not be reconciled.

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For Example,

a) Lot (b) (4), we observed 88 vials were transferred to Regen Suppliers LLC from (b) (4). While reviewing your distribution records, we discovered that 104 vials of this lot were distributed, therefore 16 vials distributed cannot be reconcilled.
b) Distribution records were not maintained for products with a (b) (4) expiration for the following dates:
   - Nov. 2023
   - Dec. 2023
   - June 2024
   - July 2024
   - Aug. 2024
   - Sept. 2024

Your firm markets and distributes human umbilical cord-derived products that include but are not limited to:

Wharton's Jelly and Exosome Products:
- Private labels: (b) (4)
- Customer private labels: (b) (4)

Umbilical Cord Blood Products:
- Private label: (b) (4)
- Customer private labels: (b) (4)

Respectively, your firm has distributed (b) (4) units marketed as Whartons Jelly labeled for (b) (4) (b) (4) units marketed as exosomes labeled for (b) (4) units marked as growth factor labeled for (b) (4) and (b) (4) units marked as cord blood marketed and labeled for "(b) (4)".

***DATES OF INSPECTION**

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11/17/2025(Mon), 11/18/2025(Tue), 11/19/2025(Wed), 11/20/2025(Thu), 11/21/2025(Fri), 11/24/2025(Mon), 12/01/2025(Mon), 12/08/2025(Mon), 12/11/2025(Thu), 12/16/2025(Tue)

X Emily S Mcgann
Investigator
Signed By: Emily S. Mcgann -S
Date Signed: 12-16-2025 08:50:28

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EMPLOYEE(S) SIGNATURE
Garrad R Poole, Investigator
Laurissa S Flowers, Investigator
Emily S Mcgann, Investigator

X Garrad R Poole
Investigator
Signed By: GARRAD R. POOLE -S
Date Signed: 12-16-2025 08:49:47

DATE ISSUED
12/16/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."